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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,315	09/08/2000	Kathleen E. Rodgers	98.009-B1	3507

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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 11/15/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/658,315

Applicant(s)

RODGERS ET AL.

Examiner

Anish Gupta

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 31-52 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,31-33 and 35-42 is/are rejected.
- 7) ☒ Claim(s) 43-52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restriction

1. The election was made with traverse to prosecute the invention of the species corresponding to SEQ. ID. No. 9 is acknowledged. In the traversal, Applicants argued that claims 35-37 read on the elected species and therefore are not drawn to a non-elected invention. Applicants request that claims 35-37 be reinstated and considered by the Examiner.

Applicant's arguments filed 8-23-02 have been fully considered but they are not persuasive.

In accordance with Markush practice, a search of the Markush-type claim was extended for claims since the art applied was that on SEQ ID 4 and SEQ ID 8 (AII (1-7) and AII(1-6) respectively). Note that SEQ ID NO. 9 was held to be free of prior art. Since Applicants are correct in that claims 35-37 read on the elected species of SEQ ID 4 and 8, they have been incorporated in the rejection. Thus claims 1-2, 31-33, 35-52 read on the elected species and claim 34 is hereby withdrawn to a non-elected species.

Claim Rejections - 35 USC § 112

2. The rejection of Claims 1-2, 31-33, 38 and 40-44 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are hereby withdraw in light of Applicants Amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 31-33, 35-38 and 40-42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mrug et al. in view of Pfeilschifter et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a method for augmenting erythropoiesis comprising contacting erythroid progenitor cells with an angiotensin II analogue.

Applicant's argue that the Pfeilschifter does not teach the effect of any compound on erythropoiesis. Further, AII (1-7) is not mediated via the AT1 receptor. The reference states that the effects of the peptide AII (1-6) and AII (1-7) are much weaker than the effects of AII. The reference does not demonstrate the effects of AII(1-6) or AII (1-7) are effective in inhibiting AT1 receptor.

Applicant's arguments filed 8-23-02 have been fully considered but they are not persuasive.

First, the sequence in the previous office action should be Asp-Arg-Val-Tyr-Ile-His instead of Asp-Arg-Val-Tyr-Val-His. Second, the reference of Pfeilschifter clearly states that "[t]he potent inhibitory action of DuP 753 and the ineffectiveness of CGP 42112A on angiotensin II induced choline and phosphatidylethanol formation (fig. 5; table 2), as well as the rank order of potency of angiotensin II, angiotensin (1-7) and angiotensin (1-6) (fig. 4) clearly show that this effect is due angiotensin II AT1 receptor activation." Thus, unlike Applicants contentions, the reference does implicate AII (1-6) and AII(1-7) in binding to AT1 receptor. Although it may be a weak interaction, the analogs never the less recognize and bind to the AT1 receptor. Therefore, since Mrug et al. teach that angiotensin II can induce erythropoiesis through the AT1 receptor, it would

have been obvious to use the peptide Asp-Arg-Val-Tyr-Val-His to simulate erythropoiesis because this peptide also shows an affinity for the AT1 receptor. Also note that the activity indicated in the Pfeilschifter et al. reference indicates the analogs had about half of the activity as AII. Given that AII was utilized at a concentration of 100nM, the dosage extrapolated for AII (1-6) and AII (1-7) would be well within the dosage range claimed.

Rejection is maintained.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-2, 31-33, 35-38 and 40-42 remain under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,239,109. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the previous office action and the reasons set forth below.

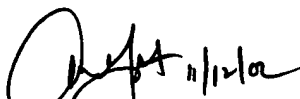
Applicants stated that a terminal disclaimer would be considered once the pending claims were otherwise allowable. Because applicant did not distinctly and specifically point out the


supposed errors in the rejection, it has been and will be maintained till a properly executed terminal disclaimer is furnished.

6. Claims 43-52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta


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